DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 6, 2014

Varian Medical Systems, Inc.
% Mr. Peter J. Coronado
Director, Regulatory Affairs
911 Hansen Way
PALO ALTO CA 94304

Re: K141336
Trade/Device Name: GammaMedplus Source Guide Tubes
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: April 11, 2014
Received: May 23, 2014

Dear Mr. Coronado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141336

Device Name
GammaMedplus Source Guide Tubes

Indications for Use *(Describe)*
The GammaMedplus Source Guide Tubes are intended to connect between the GammaMedplus Remote Afterloader system and its range of applicators. This connection creates a conduit for the source wire to travel through and allows the radioactive isotopes to be positioned within the patient´s tumor site

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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PREMARKET NOTIFICATION

510(k) Summary

GammaMedplus Source Guide Tubes

As required by 21 CFR 807.92

Submitter's Name:	Varian Medical Systems 3100 Hansen Way, m/s E-110 Palo Alto CA94304 Contact Name: Peter J. Coronado Phone: 650/424.6230 Fax: 650/ 646.9200 e-mail: submissions.support@varian.com Date: 15th May 2014
Proprietary Name:	GammaMedplus Source Guide Tubes and PDR Quick Connectors
Classification Name:	Remote controlled radionuclide applicator system 21CFR892.5700 Class II
Common/Usual Name:	Source Guide Tubes
Product code:	JAQ
Predicate Devices:	K113766 VariSource Transfer Guide Tube sets
Device Description:	Source Guide Tubes are Brachytherapy applicator accessories. Brachytherapy is a form of radiotherapy using Gamma rays from a radioactive source placed at locations close to or within a tumor or other treatment area to a predefined treatment plan. They are designed to provide a path for the dummy and source wire from the Afterloader to the Applicator. The applicator end of a Source Guide Tube can vary in design to accommodate a range of Applicators. They are intended to be used by trained and qualified personnel such as Radiation Oncologists, Physicians, Radiologists, Dosimetrists, Medical Physicists, and Nurses/MTRAs/Radiology Technicians/Radiographers in a hospital environment.
Indications for Use:	The GammaMedplus Source Guide Tubes are intended to connect between the GammaMedplus Remote Afterloader system and its range of applicators. This connection creates a conduit for the

source wire to travel through and allows the radioactive isotopes to be positioned within the patient´s tumor site.

Technological Characteristics:

Predicate Device Clearance Number:	K113766	N/A
Compatible Afterloader	VariSource Remote HDR Afterloader system	GammaMed afterloaders
Compatible Applicators	All applicators and needles that are compatible with VariSource series afterloaders	All applicators and needles that are compatible with GammaMed series afterloaders
Intended use	The VariSource Reusable transfer Guide Tubes are intended to connect between the VariSource Remote HDR Afterloader system and its range of applicators. This connection creates a conduit for the source wire to travel through and allows radioisotopes to be positioned within the patient's tumour site.	The GammaMedplus Source Guide Tubes are intended to connect between the GammaMedplus Remote Afterloader system and its range of applicators. This connection creates a conduit for the source wire to travel through and allows the radioactive isotopes to be positioned within the patient´s tumor site.
Indications for Use	Same as above	Same as above
Target population	There is no limitation to patient population. Limitations are on the maximal radiation dose applicable to the individual organs. The equipment is designed to be used by a trained and qualified Radiation Oncologist, Physician, Radiologist, Dosimetrist, Medical Physicist, and Nurse / MTRA / Radiology Technician / Radiographer	There is no limitation to patient population. Limitations are on the maximal radiation dose applicable to the individual organs. The equipment is designed to be used by a trained and qualified Radiation Oncologist, Physician, Radiologist, Dosimetrist, Medical Physicist, and Nurse / MTRA / Radiology Technician / Radiographer.
Design	Transfer Guide Tubes are designed to provide a secure connection between the VariSource afterloader and applicators, needles or catheters along which the source wire travels during Brachytherapy.	The Source Guide Tubes and PDR Quick Connectors were developed to connect between the GammaMed Afterloader systems to applicators with an internal length of: 113 mm, 180 mm, 200 mm, 250 mm 257 mm, 320 mm, 500 mm, 285 mm (Third party applicators), 187 mm (Adjustable Luer)
Materials	ABS, FEP, PEEK, Titanium, stainless steel, ABS/PP. Not in direct contact with body tissue.	FEP, Stainless Steel, PEEK, Titanium and ABS/PP. Not in direct contact with body tissue.
Packing	Individual	Individual
Sterility	Non sterile	Non sterile
Sterilization method	N/A	N/A

Biocompatibility	No body contact	No body contact
Mechanical safety	Protection caps	Protection caps
Anatomical sites	NA	NA
Compatibility with the environment and other devices	Compatible with a range of applicators, e.g. probes, needles, interstitial tubes	Compatible with a range of applicators, e.g. probes, needles, interstitial tubes
Where used	Brachytherapy treatment room	Brachytherapy treatment room

Non Clinical Tests

Bench Testing has been performed to demonstrate that

- the device functions correctly with the specified afterloader and applicators
- the device can withstand the number of cycles of use that it will experience in its lifetime;
- the device is constructed of materials that are not significantly affected by the radiation to which they are exposed in the lifetime of the product;

Usability was assessed to the requirements of IEC 62366:2007.
Results of Bench Testing showed conformance to applicable requirements and specifications

Clinical Tests No clinical tests have been included in this pre-market submission.

Conclusions All the tests that were performed met the applied pass criteria. Varian considers the devices to be safe and effective and to perform as well or better than the predicate.